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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,194	BAXTER, JEFFREY H.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) 21-37 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/18/03; 8/4/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 07/18/2003, and IDS filed 08/04/2005.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20, drawn to aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate and N-acetyl-L-glutamine, classified in class 424, subclass 400.

   II. Claims 21-37, drawn to liquid nutritional formula comprising protein, carbohydrate, lipids, and N-acetyl-L-glutamine, classified in class 424, subclass 439.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects implied by their different ingredient. The solution of Invention I may be used as dialysis solution and not for nutritional formula as required by invention II.

3. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. William Winter on July 25, 2006 a provisional election was made without traverse to prosecute the invention of I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-37 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-20 are included in the prosecution.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-20 directed to an invention not patentably distinct from claims 1-21 of commonly assigned U.S. Patent No. 6,906,038 ('038). Specifically, claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,906,038 ('038) in view of any of JP 55-105652 ('652), JP 58-018320 ('320) or US 3,178,342 ('342); and further in view of US 6,572,898 ('898), US 5,489,440 ('440) and US 5,733,579 ('579).

The present claims are directed to an aqueous solution containing 30-95 mEq sodium, 10-30 mEq potassium, 10-40 mEq citrate, 30-80 mEq chloride, less than 3% carbohydrate and N-acetyl-L-glutamine, and further comprising gelling agent, rice flour, indigestible oligosaccharide, flavor and sweetener.

The claims of US '038 are directed to an aqueous solution containing 30-95 mEq sodium, 10-30 mEq potassium, 10-40 mEq citrate, 30-80 mEq chloride, less than 3% carbohydrate.

The difference between the present claims and the claims of US '038 is that the US '038 does not claim N-acetyl-L-glutamine as claimed in claims 1-4. US '038 does not claim gelling agent as claimed in calim18, the rice flour as claimed in claim 19, or the indigestible oligosaccharides as claimed in claim 20.

JP '652 teaches aluminum salts of N-acetyl-L-glutamine solution that is highly pure and industrially advantageous to treat gastric ulcer (see the provided abstract).

JP '320 teaches aluminum salts of N-acetyl-L-glutamine solution that is free from astringent taste and useful as anti-ulcer agent (see the provided abstract).

US '342 teaches dimethyl ethanol amine salt of acetyl glutamine given orally and has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system (col.1, lines 1-18, 46-50; col.2, lines 66-67; 71; col.3, lines 1-4; claims 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, and carbohydrate as claimed by US '038, and further add aluminum salt of N-acetyl-L-glutamine as disclosed by any of the JP '652 or JP '320, motivated by the teaching of JP '652 that aluminum salt of N-acetyl-L-glutamine is highly pure and industrially advantageous to treat gastric ulcer, or motivated by the teaching of US '320 that aluminum salt of N-acetyl-L-glutamine is free from astringent taste and useful as

anti-ulcer agent , with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine that repairs the gastric mucosa effectively.

Additionally, one having ordinary skill in the art at the time of the invention would have provided an aqueous solution containing sodium, potassium, citrate, chloride, and carbohydrate as claimed by US '038, and further add dimethyl ethanol amine salt of acetyl glutamine disclosed by US '342, motivated by the teaching of US '342 that dimethyl ethanol amine salt of acetyl glutamine given orally has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system, with reasonable expectation of having aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and dimethyl ethanol amine salt of acetyl glutamine that provides nutrients to the human being as well as remarkable effect on motor system and psychic development without affecting the autonomous nervous system.

The claims of US '038 combined with any of JP '652, JP '320 or US '342, does not teach gelling agent in the composition.

US '898 teaches convenient, non-threatening, and easy to administer rehydration composition comprising electrolyte and gelling agent to be consumed by children and elderly who cannot tolerate liquid or frozen formulations (abstract; col.5, lines 1-3). The gelling agent includes carrageenan, agar, alginate, or gums (col.5, line 61-col.6, line 9). The composition comprises electrolytes and carbohydrate (col.3, lines 115-26; col.6, lines 28-30; col.9, example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine as taught by the combination of US '038 and any of JP '652, JP '320 or US '342, and further add gelling agent as disclosed by US '898, motivated by the teaching of US '898 that gelling agents provides a convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen formulations, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and gelling agent wherein the composition is convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen formulations.

The claims of US '038 combined with any of JP '652, JP '320 or US '342, does not teach rice flour as claimed in claim 19.

US '440 teaches oral rehydration solution comprising rice flour that resulted in lower net fluid intake and reduced stool output during rehydration period of treatment (abstract; col.3, lines 51-55)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine as taught by the combination of US '038 and any of JP '652, JP '320 or US '342, and further add rice flour to the composition as disclosed by US '440, motivated by the teaching of US '440

that rice flour results in lower net fluid intake and reduced stool output during rehydration period of treatment, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and rice flour that treats hydration effectively.

The claims of US '038 combined with any of JP '652, JP '320 or US '342, does not teach indigestible oligosaccharides as claimed in claim 20.

US '579 teaches oral rehydration solution comprises indigestible oligosaccharide that shown to have beneficial impact on microbial flora of the intestine, reduces serum cholesterol, and also alleviates constipation (abstract; col.5, line 64-col.6, line 12).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine as taught by the combination of US '038 and any of JP '652, JP '320 or US '342, and further add indigestible oligosaccharide as disclosed by US '579, motivated by the teaching of US '579 that indigestible oligosaccharide shown to have beneficial impact on microbial flora of the intestine, reduces serum cholesterol, and also alleviates constipation, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and indigestible oligosaccharide, wherein the composition treats hydration without altering the intestinal flora, and further reduces serum cholesterol.

9. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,906,038 ('038), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is improperly depending on itself. Accordingly, claims 2-6 and 8-20 are improperly dependant on claim 7.

Claims 7, 8, 10 fail to further limit the subject matter of a previous claim 1. Claim 7 recite the same quantity of carbohydrate as recited in claim 1, claim 8 recite the same quantity of sodium as recited in claim 1, and claim 10 recite the same quantity of potassium as recited in claim 1.

Claim 4 recites the limitation "nutritionally acceptable salts" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 8, 9 recite the limitation "sodium" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 10 and 11 recites the limitation "potassium" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 12 and 13 recite the limitation "chloride" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 14 and 15 recite the limitation "citrate" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

For prosecution purposes, claims 2-20 will be treated as depending on claim 1.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-3, 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 540 462 ('462) in view of US 6,572,898 ('898).

EP '462 teaches liquid nutritional solution comprising N-acetyl-L-glutamine salts (abstract; page 2, lines 42-44, 55-58; page 3, lines 57-58). The amount of glutamine given ranges from 0.1 to 70 g/kg/ day (page 3, lines 9-15), and these amounts are calculated to be equal to 0.532 to 37.24 mmol/kg/day, i.e. applicant's claimed amounts fall within the disclosure of the reference. When glutamine added to drink, it does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability (page 2, lines 49-50). EP '462 teaches that the liquid formulation further comprises carbohydrate such as dextrose and fructose, and electrolytes including sodium, potassium and chloride (page 3, lines 23-26, 40-54; page 4, lines 7-26). The composition comprises flavoring agent and the like (page 2, line 58).

However, EP '462 does not teach the amounts of sodium, potassium and chloride and their salts as instantly claimed, citrate in the solution and its amount, and gelling agents as claimed in claim 18. EP '462 does not teach sweetener as claimed in claim 17.

US '898 teaches convenient, non-threatening, and easy to administer rehydration composition comprising electrolyte and gelling agents to be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte (abstract; col.5, lines 1-3). The composition comprises from 20-60 mEq of sodium per liter, 15-25 mEq of potassium per liter, 25-50 mEq of chloride per liter, and 20-50 mEq of citrate per liter

(col.3, lines 115-26). The carbohydrate included fructose and dextrose and is present in an amount of 2.473 wt % (col.6, lines 28-30; col.9, example 1). The gelling agent includes carrageenan, agar, alginate, or gums (col.5, line 61-col.6, line 9). The composition further comprises flavoring agent and sweeteners (col.6, lines 41-43).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide solution comprising solution comprising N-acetyl-L-glutamine salts, carbohydrate sodium, potassium and chloride as disclosed by EP '462, and further add gelling agent and citrate, and adjust the amount to the amounts disclosed by US '898, motivated by the teaching of US '898 that the disclosed composition comprising citrate and other electrolytes in the disclosed amounts help rehydration treatment, and gelling agents provides a convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen formulations, with reasonable expectation of having composition comprising N-acetyl-L-glutamine salts, carbohydrate sodium, potassium, chloride, and citrate in the claimed amounts, and further comprising gelling agent that makes the composition more tolerable by children and elderly, convenient, non-threatening, and easy to administer.

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 540 462 ('462) in view of US 6,572,898 ('898), and further in view of any of JP '652, JP '320 or US '342.

The teachings of EP '462 combined with US '898 are discussed above.

However, the combined teachings of EP '462 and US '898 does not teach the specific glutamine salts as claimed in claim 4.

JP '652 teaches aluminum salts of N-acetyl-L-glutamine solution that is highly pure and industrially advantageous to treat gastric ulcer (see the provided abstract).

JP '320 teaches aluminum salts of N-acetyl-L-glutamine solution that is free from astringent taste and useful as anti-ulcer agent (see the provided abstract).

US '342 teaches dimethyl ethanol amine salt of acetyl glutamine given orally and has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system (col.1, lines 1-18, 46-50; col.2, lines 66-67; 71; col.3, lines 1-4; claims 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and select the aluminum salts of N-acetyl-L-glutamine as disclosed by any of the JP '652 or JP '320, motivated by the teaching of JP '652 that aluminum salt of N-acetyl-L-glutamine is highly pure and industrially advantageous to treat gastric ulcer, or motivated by the teaching of US '320 that aluminum salt of N-acetyl-L-glutamine is free from astringent taste and useful as anti-ulcer agent , with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine that repairs the gastric mucosa effectively.

Additionally, one having ordinary skill in the art at the time of the invention would have provided an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and select dimethyl ethanol amine salt of acetyl glutamine disclosed by US '342, motivated by the teaching of US '342 that dimethyl ethanol amine salt of acetyl glutamine given orally has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system, with reasonable expectation of having aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and dimethyl ethanol amine salt of acetyl glutamine that provides nutrients to the human being as well as remarkable effect on motor system and psychic development without affecting the autonomous nervous system.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view of US '898 and further in view of US '440.

The teachings of EP '462 combined with US '898 are discussed above.

However, the combined teaching of EP '462 and US '898 does not teach rice flour in the composition as claimed by claim 19.

US '440 teaches oral rehydration solution comprising rice flour that resulted in lower net fluid intake and reduced stool output during rehydration period of treatment (abstract; col.3, lines 51-55)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium,

citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and further add rice flour to the composition as disclosed by US '440, motivated by the teaching of US '440 that rice flour results in lower net fluid intake and reduced stool output during rehydration period of treatment, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and rice flour that treats hydration effectively.

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view of US '898 and further in view US '579.

The teachings of EP '462 combined with US '898 are discussed above. However, the combined teaching of EP '462 and US '898 does not teach indigestible oligosaccharides as claimed in claim 20.

US '579 teaches oral rehydration solution comprises indigestible oligosaccharide that shown to have beneficial impact on microbial flora of the intestine, reduces serum cholesterol, and also alleviates constipation (abstract; col.5, line 64-col.6, line 12).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and further add indigestible oligosaccharide as disclosed by US '579, motivated by the teaching of US '579 that indigestible oligosaccharide shown to have beneficial impact on microbial flora of the intestine,

reduces serum cholesterol, and also alleviates constipation, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and indigestible oligosaccharide, wherein the composition treats hydration without altering the intestinal flora, and further reduces serum cholesterol.

17. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being obvious over US '038 in view of any of JP '652, JP '320 and US '342, and further in view of US '898 as applied to claim 18.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '038 teaches an aqueous solution containing 30-95 mEq of sodium ions, 10-30 mEq of potassium ions, 10-40 mEq of citrate, 30-80 mEq of chloride, less than 3% of carbohydrate such as fructose and dextrose, glutamine derivatives, gelling agent, rice flour, and indigestible oligosaccharide, and further comprising flavor and sweetener (abstract; col.4, lines 12-67; col.5, lines 1-20, 36-40, 57060; col.6, lines 21, claims 1-21).

However, US '038 does not teach the specific salts of glutamine as instantly claimed in claims 1 and 4, or the specific gelling agents as instantly claimed in claim 18.

Applicants failed to show superior and unexpected results from using specific glutamine salts or specific gelling agents, therefore, they do not impart patentability to the claims.

JP '652 teaches aluminum salts of N-acetyl-L-glutamine solution that is highly pure and industrially advantageous to treat gastric ulcer (see the provided abstract).

JP '320 teaches aluminum salts of N-acetyl-L-glutamine solution that is free from astringent taste and useful as anti-ulcer agent (see the provided abstract).

US '342 teaches dimethyl ethanol amine salt of acetyl glutamine given orally and has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system (col.1, lines 1-18, 46-50; col.2, lines 66-67; 71; col.3, lines 1-4; claims 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium,

citrate, chloride, carbohydrate and glutamine as disclosed by US '038, and select aluminum salt of N-acetyl-L-glutamine as disclosed by any of the JP '652 or JP '320, motivated by the teaching of JP '652 that aluminum salt of N-acetyl-L-glutamine is highly pure and industrially advantageous to treat gastric ulcer, or motivated by the teaching of US '320 that aluminum salt of N-acetyl-L-glutamine is free from astringent taste and useful as anti-ulcer agent , with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and aluminum salt of N-acetyl-L-glutamine that repairs the gastric mucosa effectively.

Additionally, one having ordinary skill in the art at the time of the invention would have provided an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate and glutamine as disclosed by US '038, and select dimethyl ethanol amine salt of acetyl glutamine disclosed by US '342, motivated by the teaching of US '342 that dimethyl ethanol amine salt of acetyl glutamine given orally has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system, with reasonable expectation of having aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and dimethyl ethanol amine salt of acetyl glutamine that provides nutrients to the human being as well as remarkable effect on motor system and psychic development without affecting the autonomous nervous system.

The combined teaching of US '038 and any of JP '652, JP '320 or US '342 does not teach the specific gelling agents as claimed in claim 18.

US '898 teaches convenient, non-threatening, and easy to administer rehydration composition comprising electrolyte and gelling agent to be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte (abstract; col.5, lines 1-3). The gelling agent includes carrageenan, agar, alginate, or gums (col.5, line 61-col.6, line 9). The composition comprises electrolytes and carbohydrate (col.3, lines 115-26; col.6, lines 28-30; col.9, example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, glutamine salts, and gelling agent as taught by US '038 combined with any of JP '652, JP '320 or US '342, and select carrageenan, agar, alginate, or gums disclosed by US '898, motivated by the teaching of US '898 that these gelling agents provides a convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and gelling agent such as carrageenan, agar, alginate, or gums, wherein the composition is convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen compositions.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali
Examiner
Art Unit 1615

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